UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

HARVINDER S. SANDHU, M.D., and KYPHON INC., Plaintiffs, v. MEDTRONIC SOFAMOR DANEK, INC., MEDTRONIC SOFAMOR DANEK USA, INC., and SDGI HOLDINGS, INC., Defendants.	Court File No. 2:05-2863-MI V

KYPHON'S OPPOSITION TO MEDTRONIC'S MOTION FOR PARTIAL SUMMARY JUDGMENT FOR INVALIDITY OF THE '404 PATENT UNDER 35 U.S.C. § 112 AND MEMORANDUM IN SUPPORT OF KYPHON'S MOTION FOR SUMMARY JUDGMENT OF NO INVALIDITY UNDER THE WRITTEN DESCRIPTION REQUIREMENT OF 35 U.S.C. § 112

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Kyphon (11/6/06) Ex. 56	Deposition Transcript of Dr. Stephen M. Belkoff
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[1] Exhibits cited are attached to Plaintiff's November 6, 2006 Appendix of Exhibits.

I. INTRODUCTION

Medtronic has moved for summary judgment of invalidity of Kyphon's U.S. Patent No. 5,108,404 ("'404 patent") on the grounds that it fails to satisfy the written description requirement. Leaving aside that the written description requirement is an issue of fact for the jury, that on summary judgment all factual inferences have to be drawn in Kyphon's favor, and that invalidity must be proven by clear and convincing evidence, Medtronic's motion fails simply because there is no written description problem here. The written description of the '404 patent allows one of ordinary skill in the art to recognize that the inventors invented what is claimed: a method of treating bone fractures by inserting a device into the bone to create a passage, compacting the bone tissue to increase the volume of that passage, and filling the passage with (for instance) bone cement. This brief, the deposition testimony of Medtronic's own expert, and the declarations of Dr. Michael Marks and Dr. Harvinder Sandhu filed in support of this brief demonstrate just that.

In addition to opposing Medtronic's motion, Kyphon therefore moves for summary judgment of no invalidity under the written description requirement of 35 U.S.C. § 112.

II. LEGAL STANDARDS

A. Summary Judgment Standard

Summary judgment under Rule 56 of the Federal Rules of Civil Procedure is appropriate when the evidence presented shows that no genuine issue of material fact exists and the moving party is entitled to a judgment as a matter of law. FED. R. CIV. P. 56(c); *Shah v. Racetrac Petroleum Co.,* 338 F.3d 557, 566 (6th Cir. 2003). To make this determination, the Court must decide "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 251-52, 106 S. Ct. 2505 (1986). Evidence suggesting only a "mere

possibility" of a factual dispute is not enough to preclude summary judgment. *Shah* at 566. The standard of review for cross-motions for summary judgment is the same as the standard applied when only one party files such a motion. *Taft Broad. Co. v. U.S.,* 929 F.2d 240, 248 (6th Cir. 1991).

B. Medtronic Must Show Invalidity by Clear and Convincing Evidence

The already-demanding standard for obtaining summary judgment is even more difficult to meet by a party seeking to have a patent declared invalid. Under Fed. R. Civ. P. 56, a party must show that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." In the context of a validity challenge, this standard is significantly higher because a patent is entitled to a presumption of validity. 35 U.S.C. § 282. This presumption is particularly strong here because, as part of the examination process, patent examiners are tasked with assessing whether the patent satisfies the written description requirement. *See In re Alton*, 76 F.3d 1168, 1170 (Fed. Cir. 1996) (vacating the Patent Office's decision that the patent did not satisfy the written description requirement, and remanding for further proceedings). The presumption of validity can be overcome only by clear and convincing evidence. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 715-16 (Fed. Cir. 1991). "Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Eli Lilly & Co. v. Barr Labs., Inc.*, 222 F.3d 973, 980 (Fed. Cir. 2000). *See Anderson* at 248 (holding that heightened standard of clear and convincing evidence—which here would be Medtronic's burden at trial—is to be considered when evaluating the sufficiency of the evidence on motion for summary judgment).

C. The Written Description Analysis Focuses on the Claims

Under 35 U.S.C. § 112, paragraph 1, a patent applicant must include a written description of the invention in the specification to "allow persons of ordinary skill in the art to recognize that [the applicant] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989). Accordingly, the analysis focuses on "whether the disclosure of the application . . . 'reasonably

conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'" *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir 1991) (internal citations omitted). Moreover, because "[t]he invention is, for the purposes of the 'written description' inquiry, *whatever is now claimed,*" *id.* at 1564 (emphasis in original), the analysis focuses first on the claims themselves.

Claims need not be limited to a preferred embodiment, and a specification can support claims broader than the particular embodiments disclosed. *Fuji Photo Film Co., LTD v. Int'l Trade Comm'n*, 386 F.3d 1095, 1106 (Fed. Cir. 2004) (refusing to limit a claim to 'in a darkroom,' despite that being the single method described in the specification for protecting film, because "[a]bsent a clear indication in the specification that the invention was limited to processes performed entirely in a darkroom, or evidence that a person of ordinary skill in the art of designing cameras would not have known how to perform those steps anywhere but in a darkroom, the scope of claim 1 is not limited to the particular method of avoiding premature exposure that was described in the specification."); *Cordis Corp. v. Medtronic AVE, Inc.*, 339 F.3d 1352, 1364-65 (Fed. Cir. 2003) (affirming that 'plurality of slots' was not limited to the preferred embodiment with multiple types of slots); *Lampi Corp. v. Am. Power Prods., Inc.*, 228 F.3d 1365, 1378 (Fed. Cir. 2000) (affirming that the specification did not limit the invention to 'identical half-shells' but also supported broader, non-identical 'half-shells'). Because the specification is written for one skilled in the art, the knowledge of such a person is critical to understanding whether the claims are adequately described. *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1126 (Fed. Cir. 2004) (remanding for failure to consider what one skilled in the art would have understood from the disclosure).

D. The § 112 Written Description Defense is a Question of Fact That Must Be Proven By Clear and Convincing Evidence

Because a patent is presumed valid once issued, a defendant must prove invalidity due to lack of written description by clear and convincing evidence. *See* 35 U.S.C. § 282. The adequacy of written description is a question of fact to be decided on a case-by-case basis. *Vas-*

Cath, Inc., 935 F.2d at 1562-63. Consequently, the Federal Circuit rarely affirms summary judgments of invalidity based on written description. *Hoechst Celanese Corp v. BP Chem. Ltd.*, 844 F. Supp. 336 (S.D. Tex. 1994), *aff'd in part, vacated in part*, 65 F.3d 188 (Fed. Cir. 1995) (unpublished) (reviewing published Federal Circuit opinions between 1990 and 1994 in which the Circuit reviewed district court summary judgments of invalidity, and finding only two that were not reversed). In fact, since 1994, the Federal Circuit has, more often than not, *reversed* summary judgment of invalidity under §112.[2] Certainly summary judgment of invalidity under §112 is the exception, not the rule, and the exception does not apply here.

> Kyphon's burden on its motion or summary judgment is not so demanding:
>
> a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise. Alternatively, a moving party seeking to have a patent held not invalid at summary judgment must show that the nonmoving party, who bears the burden of proof at trial, failed to produce clear and convincing evidence on an essential element of a defense upon which a reasonable jury could invalidate the patent

Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 962 (Fed. Cir. 2001). If Medtronic fails to present adequate evidence sufficient to meet its extraordinary burden of clear and convincing evidence at trial, a summary judgment for Kyphon is appropriate. *See Celotex Corp. v. Catrett*, 477 U.S. 317 (1986) (". . . the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.").

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[2] The Federal Circuit has reversed grants of summary judgment of invalidity under the written description requirement in eight out of eleven cases since 1994. *See Space Sys./Loral, Inc. v. Lockheed Martin Corp.*, 405 F.3d 985 (Fed. Cir. 2005); *MercExchange, L.L.C. v. eBay, Inc*., 401 F.3d 1323 (Fed. Cir. 2005); *ICN Photonics, LTD. v. Cynosure, Inc.*, 73 Fed. Appx. 425 (Fed. Cir. 2003) (non-precedential); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956 (Fed. Cir. 2002); *All Dental Prodx. L.L.C. v. Advantage Dental Prods., Inc.*, 309 F.3d 774 (Fed. Cir. 2002); *Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317 (Fed. Cir. 2002); *Total Containment, Inc. v. Intelpro Corp.*, 217 F.3d 852 (Fed. Cir. 1999) (non-precedential); *Reiffin v. Microsoft Corp.*, 214 F.3d 1342 (Fed. Cir. 2000) (reversing grant of summary judgment of invalidity based on written description).

III. KYPHON'S STATEMENT OF UNDISPUTED FACTS[3]

A. The '724 Application and the '888 Patent

1. On February 9, 1989, U.S.S.N. 308,724 "Surgical Protocol For Fixation Of Osteoporotic Bone Using Inflatable Device" ("the '724 application") was filed by Arie Scholten and Mark Reiley.

2. Claim 1 as initially filed read:

> A method of fixation of a fracture or impending fracture of an osteoporotic bone comprising:
>
> [1] forming a passage in the bone;
>
> [2] increasing the volume of said passage; and
>
> [3] filling the passage with a flowable material capable of setting to a hardened condition.

[Medtronic Ex. 2.D, '888 Patent Prosecution History, Application, Claim 1, at 18 (February 9, 1989).] Thus, claim 1 as filed was not limited to the use of inflatable, or even expandable devices.

3. On August 26, 1989, the Patent Examiner issued a rejection of the '724 application under 35 U.S.C. § 112. This rejection related to the indefiniteness requirement and not the written description requirement. [Medtronic Ex. 2.D, '888 Patent Prosecution History, Office Action, at 2-3 (August 26, 1989).]

4. The August 26, 1989 rejection was cured by amendment. [Medtronic Ex. 2.D, '888 Patent Prosecution History, Amendment, at 8 (November 28, 1989) and Notice of Allowability (March 15, 1990).]

5. The '724 application issued as U.S. Patent No. 4,969,888, "Surgical Protocol for Fixation of Osteoporotic Bone Using Inflatable Device," ("the '888 patent") on November 13, 1990. [Medtronic Ex. 1.D, '888 Patent.]

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[3] Kyphon's response to Medtronic's "Statement of Undisputed Facts" is attached as Appendix A to this brief.

B. The '862 Application and the '404 Patent

6. On August 15, 1990, U.S.S.N. 567,862, "Surgical Protocol For Fixation of Bone Using Inflatable Device" ("the '862 application") was filed by Arie Scholten and Mark Reiley as a continuation-in-part of the '724 application/'888 patent.

7. Claim 1 as filed in the '862 application reads:

> A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:
>
> [1] forming a passage in the bone marrow;
>
> [2] compacting the bone marrow to increase the volume of said passage; and
>
> [3] filling the passage with a flowable material capable of setting to a hardened condition.

[Medtronic Ex. 2.C, '404 Patent Prosecution History, Application, Claim 1, at 18 (August 15, 1990).]

8. Claim 1 of the '862 application is not limited to an inflatable (balloon) device. [Medtronic Ex. 2.C, '404 Patent Prosecution History, Application, Claim 1, at 18 (August 15, 1990).]

9. There was only one office action during the prosecution of the '862 application. [*See* Medtronic Ex. 2.C, '404 Patent Prosecution History, Office Action (June 24, 1991).]

10. The entire prosecution of the '862 application lasted less than two years. [*See* Medtronic Ex. 2.C, '404 Patent Prosecution History.]

11. The '862 application issued as U.S. Patent No. 5,108,404 ("the '404 patent") without any changes to claim 1 on April 28, 1992. [*See* Medtronic Ex. 2.C, '404 Patent Prosecution History.]

12. Claim 12 of the '404 patent depends from claim 1:

> A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.

[*See* Medtronic Ex. 1.C, '404 patent, col. 10, lines 11-13.]

13. Neither claim 1 nor claim 12 of the '404 patent is limited to an inflatable (balloon) device. [Medtronic Ex. 1.C, '404 patent, col. 1, lines 33-41 and col. 10, lines 11-13.]

14. Claim 5 of the '404 patent depends from claim 1:

> A method as set forth in claim 1, wherein said compacting step includes inflating an inflatable device in said passage to urge the bone marrow therein.

[*See* Medtronic Ex. 1.C, '404 patent, col. 9, lines 53-55.]

15. Unlike claims 1 and 12 of the '404 patent, claim 5 of the '404 patent is limited to an inflatable (balloon) device. [*See* Medtronic Ex. 1.C, '404 patent, col. 1, lines 33-41, col. 10, lines 11-13, and col. 9, lines 53-55.]

C. The Delaware Litigation

16. In 2004, Kyphon sued Disc-O-Tech ("DOT") alleging infringement of several patents, including the '404 patent. [*See* Medtronic Ex. 28, Complaint, *Kyphon, Inc. v. Disc-O-Tech Med. Techs., Ltd.,* C.A. No. 04-204-JJF (April 2, 2004 D. Del.).] (the "Delaware Litigation").

17. During the Delaware Litigation, DOT argued that the "compacting" step in claim 1 should be interpreted to require the use of inflatable (balloon) devices. [*See* Medtronic Ex. 24, Special Master's Opinion and Order on Claim Construction, at 4; *see also* Kyphon Ex. 62, *Kyphon Inc. v. Disc-O-Tech Medical Techs. Ltd.,* 2004 WL 2898064 at *4 (D. Del. 2004) (not reported in F. Supp. 2d.).]

18. On May 16, 2005, a Special Master in the Delaware Litigation ruled that the claim 1 "compacting" step was not limited to only using inflatable (balloon) devices. [Medtronic Ex. 24, Special Master's Opinion and Order on Claim Construction, at 9.] Importantly, this ruling was adopted by the District Court without amendment. [Kyphon Ex. 26, Transcript of Pretrial Conference, June 16, 2005.]

19. The Court in the Delaware Litigation likewise rejected DOT's written description defense, presented in opposition to Kyphon's motion for a preliminary injunction. [Kyphon Ex. 62, *Kyphon Inc.*, 2004 WL 2898064 at *4 (D. Del. 2004) (not reported in F. Supp. 2d.).]

D. Medtronic's Expert on Invalidity

20. Dr. Stephen Belkoff, Medtronic's expert who submitted a declaration in support of Medtronic's §112 motion, does not understand the clear and convincing standard for invalidity, nor did he apply that standard while preparing his Declaration filed in support of Medtronic's §112 summary judgment motion. [*See* Kyphon Ex. 56, Deposition of Dr. Stephen Belkoff, 35:11-36:19 (October 27, 2006).]

21. Dr. Belkoff did not consider the Examiner's determination on written description in forming his opinion on validity. [*See* Kyphon Ex. 56, Deposition of Dr. Stephen Belkoff, 34:1-35:10 (October 27, 2006).]

IV. THE '404 PATENT SATISFIES THE WRITTEN DESCRIPTION REQUIREMENT

A. The Decision in the Delaware Litigation

As with many of the issues in this case, the written description issue is not a clean slate. The District of Delaware, in the preliminary injunction proceedings in *Kyphon Inc. v. Disc-O-Tech Medical Technologies Ltd.*, already rejected Medtronic's written description argument:

> Disc-O contends that Claim 1 of the '404 patent is invalid for a lack of sufficient written description as required by 35 U.S.C. § 112 paragraph 1. In support of this contention, Disc-O argues that the written description of the patent discloses only the compaction of bone marrow through the use of an inflatable device. In Disc-O's view, to the extent that Claim 1 seeks to cover any other means of compacting bone marrow, it is invalid under § 112.
>
> Pursuant to § 112 paragraph 1, the written description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. *In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989). Each and every element originally described by the inventor as being a part of his invention are the 'essential elements' of the invention. *See Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479 (Fed. Cir. 1998). These essential elements must appear in the claims ultimately issued in the patent. *Id.*
>
> The Court finds that the patent does not state that an inflatable device is an essential element of the invention or that it is the only possible embodiment for achieving the claimed invention of compacting the bone marrow. Thus, the Court concludes that the '404 patent is not invalid for a lack of sufficient written description as required by 35 U.S.C. § 112 paragraph 1.

Kyphon Inc., 2004 WL 2898064 at *4 (D. Del. 2004) (not reported in F. Supp. 2d.) [Kyphon Ex. 62]. While not binding on this Court, this Court may find the Delaware Court's perspective relevant in addressing the same issue.

B. Claims 1 and 12 of the '404 Patent Are Not Limited to Balloons, and the Written Description Has Supported These Broad Claims Since the Patent Was Filed

The '404 patent claims the formation of a passage in bone marrow, the use of a device to compact bone tissue to enlarge that passage, and the filling of the resulting void with a flowable material like bone cement. Medtronic argues that the patent violates the written description requirement because the embodiments described in the specification use an inflatable device to compact the bone tissue, while the claims are broader. But it is black letter law that you cannot import limitations from the specification into the claims. *Burke, Inc. v. Bruno Independent Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999). The crux of Medtronic's argument is that the claim term "compacting the bone marrow" should really be read as "compacting the bone marrow with an inflatable device," and if it is not, the claim is invalid. But, as the Federal Circuit has stated: "[C]laim terms cannot be narrowed by reference to the written description or prosecution history unless the language of the claims invites reference to those sources." *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989-90 (Fed. Cir. 1999). This is based on long-standing Supreme Court reasoning: "[I]f we once begin to include elements not mentioned in the claim, in order to limit such claim . . ., we should never know where to stop." *McCarty v. Lehigh Valley R.R.*, 160 U.S. 110, 116 (1895).

The Federal Circuit has held time and again that in conducting a written description analysis "[i]t is to the *claims* which particularly point out what the inventor regards as his invention that one must look, and each claim must be considered separately." *Stiftung v.*

Renishaw PLC, 945 F.2d 1173, 1181 (Fed. Cir. 1991) (emphasis added); *see also Sun Microsystems, Inc. v. Kingston Tech. Co.,* 57 U.S.P.Q.2d 1822, 1823 (N.D. Cal. 2000) ("the written description requirement requires that each claim is supported by the specification of the patent at issue. The initial reference point must be the claim itself."). Here, Medtronic ignores the claim language, directing the inquiry to the specification where it highlights only the sections that discuss balloons.[4]

An originally filed claim can provide the requisite written description to satisfy § 112. *LizardTech, Inc. v. Earth Res. Mapping, Inc*., 424 F.3d 1336, 1346 (Fed. Cir. 2005) (citing *Union Oil Co. of Cal. v. Atlantic Richfield Co*., 208 F.3d 989, 998 n.4 (Fed. Cir. 2000)). An analysis of the claims here, as filed and as issued, clearly shows the adequacy of the written description. Claim 1, as originally filed, and as later issued, was never limited to using a balloon to perform the claimed method. This claim language clearly describes to one of skill in the art the full breadth of the claimed surgical method, and that it is not limited to the use of a balloon. [*See* Medtronic Ex. 2.C, '404 Patent Prosecution History, Application, Claim 1, at 18 (August 15, 1990); Ex. 1.C, '404 Patent, col. 9, lines 33-41; *see also* Kyphon Ex. 35, Declaration of Dr. Michael Marks, ¶¶ 73-74; Kyphon Ex. 36, Declaration of Dr. Harvinder Sandhu, ¶¶ 33-34.] Thus, the claims as originally filed clearly show that the inventors had in mind a surgical procedure that was not limited to the use of inflatable devices.

If there could be any doubt at all, Claim 5, as originally filed, and as later issued, lays those doubts to rest. Claim 5 has always included the added limitation "wherein said compacting step includes inflating an inflatable device in said passage to urge the bone marrow therein." This limitation would be meaningless if Claim 1 were limited to the use of inflatable devices to compact the bone marrow. Thus, Claim 5 confirms that Claim 1 is properly read more broadly.

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[4] Medtronic also relies heavily on *other* Kyphon patents, in which it claims "Kyphon publicly confirmed that the '404 patent ***only*** disclosed a balloon for performing the compacting step." [Medtronic Mot. at 7 (emphasis added).] This is inaccurate. Each of these patents does indeed confirm that the '404 patent discloses a balloon for performing the compacting step. That is undisputed. But a review of the passages quoted by Medtronic shows that these other Kyphon patents do ***not*** make the affirmative representation that the '404 patent written description supports nothing ***more*** than a balloon.

Moreover, after the Patent Office reviewed the '404 patent for the sufficiency of the written description, it issued the patent. Indeed, the Patent Examiner even issued a rejection under 35 U.S.C. § 112, ***but not for the written description requirement.***[5] [*See* Medtronic Ex. 2.D, '888 Patent Prosecution History, Office Action, at 2-3 (August 26, 1989).] This is not a situation where broader claims snuck in during a protracted prosecution. Indeed, there was but a single office action, and the entire prosecution lasted less than two years. [*See* Medtronic Ex. 2.D, '888 Patent Prosecution History and Ex. 2.C, '404 Patent Prosecution History.]

The fact that the '404 patent claims the 3-step method of treating bone fracture broadly—without limiting that method to the use of a balloon for the second step—makes sense technically as well. The new method invented by Dr. Reiley and Mr. Scholten—forming a passage, increasing the volume of the passage by compaction, and filling the passage with a particular material—was, as the Patent Office found, new, useful, and non-obvious. The use of a balloon to accomplish the second step, while being an elegant and creative solution, is not necessary to achieve the results of the invention. Indeed, Disc-O-Tech was found—on summary judgment—to infringe Kyphon's '404 and '888 patents, and the Disc-O-Tech device was not a balloon; instead, it was a mechanically expandable device just as Medtronic's is. Just as you can make a chocolate soufflé using any of a number of tools to whip the egg whites—a stand mixer, an electric hand mixer, a hand-crank egg-beater, or a fork—you can perform Dr. Reiley's and Mr. Scholten's surgical method with any number of cavity-creating compacting tools—Kyphon's balloons, Disc-O-tech's device,[6] or Medtronic's Arcuate XP.

Aside from the patent and the prosecution history, the only evidence submitted by Medtronic is the declaration of Dr. Stephen Belkoff. But Dr. Belkoff's declaration does not address the claim language of claims 1 and 5. Further, Dr. Belkoff confirmed in deposition that he did not know about the clear and convincing evidence standard for invalidity [Kyphon Ex. 56,

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[5] This rejection related to the definiteness requirement, and was cured by amendment. [*See* Medtronic Ex. 2.D, '888 Patent Prosecution History, Office Action, at 2-3 (August 26, 1989).]

Deposition of Dr. Stephen Belkoff, 35:11-36:19 (October 27, 2006)], and that he had not considered, and did not have an opinion about, the Patent Examiner's determination on written description. [Kyphon Ex. 56, Deposition of Dr. Stephen Belkoff, 34:1-35:10 (October 27, 2006)].

Indeed, Medtronic has failed to present evidence that would be in any way adequate to meet its extraordinary burden of clear and convincing evidence at trial. For that reason, not only is it appropriate for the Court to deny Medtronic's motion for partial summary judgment on this issue, but Kyphon respectfully requests the Court enter partial summary judgment in favor of Kyphon on this issue. *Celotex*, 477 U.S. 317.

C. The "Essential Element" Test Is Not Appropriate

Medtronic avoids citing the oft-rejected "essential element" test by name, but this is precisely the argument it makes. Medtronic argues that the claims in Kyphon's patents require a particular element (an inflatable device) in order to be supported by the disclosure. But the Supreme Court has rejected the idea that patents have "essential elements," *Aro Mfg. Co. v. Convertible Top Replacement Co.,* 365 U.S. 336, 345, 5 L. Ed. 2d 592, 81 S. Ct. 599 (1961) (there is "no legally recognizable or protected 'essential' element . . . in a combination patent."), and the Federal Circuit has rejected—or at least severely limited—the "omitted essential element" test, recognizing that "the specification must of course describe the claimed invention, [but] it is well established that the claims need not include every component that is described in the specification," *Reiffin*, 214 F.3d at 1347; *see also Cooper Cameron Corp. v. Kvaerner Oilfield Prods., Inc.*, 291 F.3d 1317, 1323 (Fed. Cir. 2002) ("we did not announce a new 'essential element' test mandating an inquiry into what an inventor considers to be essential to his invention and requiring that the claims incorporate those elements"); *Bayer AG v. Sony Elecs., Inc.*, 229 F. Supp. 2d 332, 360 (D. Del. 2002) ("the Court is not persuaded that the 'omitted element test' is a viable ground upon which to declare a patent invalid."); *Sun*

[6] Pursuant to a consent judgment and injunction, Disc-O-Tech's device is no longer sold in the United States. [Kyphon Ex. 59, Consent Judgment and Injunction.]

Microsystems, 57 U.S.P.Q.2d at 1823 (rejecting the essential element test as "unworkable" and "counterproductive"); *Reiffin*, 158 F. Supp. 2d at 1024 ("the issue whether Reiffin's patents are valid must be addressed without applying the omitted element test"). Even if the essential element test were viable, as the Delaware District Court agreed, there is no suggestion in the '404 patent that a balloon is "essential" to compacting bone.

Medtronic's reliance on *LizardTech, Inc.* is misplaced. In *Lizardtech*, the Federal Circuit held that claims directed to a general method for creating a "Seamless Discreet Wavelet Transform" were not supported by a disclosure that only described one particular method for creating one. *LizardTech*, 424 F.3d at 1346. While *LizardTech* is distinguishable for many reasons (not the least of which is that a person skilled in the art would recognize that Kyphon's patent ***does*** support the surgical method performed by devices other than balloons), the "seamless DWT" element in *LizardTech* was also specifically claimed. In the Kyphon patents, however, a "balloon" element is not claimed.

Also, in *LizardTech*, the "seamless DWT" element was essential to the problem to be solved, and distinguished the prior art. In the words of the Federal Circuit: "While it is true that not every advantage of the invention must appear in every claim, it would be peculiar for the claims to cover prior art that suffers from precisely the same problems that the specification focuses on solving." *Lizardtech* at 1343-44 (internal citation omitted). Here, by contrast, the long-felt need for a treatment for vertebral compression fractures is met by the claimed surgical method: forming a passage, compacting the bone marrow to increase the volume of that passage, and filling the passage with a flowable material that sets to a hardened condition. The particular device used for compacting the bone marrow and increasing the volume of the passage is of no import with regard to infringement of this method claim.

V. CONCLUSION

For these reasons, Kyphon urges the Court to deny Medtronic's motion for summary judgment of invalidity of the '404 patent for failure to satisfy the written description requirement. Instead, Kyphon respectfully requests that the Court enter summary judgment

rejecting Medtronic's written description defense and holding that, as a matter of law, Claims 1 and 12 of the '404 patent are not invalid.

Dated: November 7, 2006

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Appendix A

Kyphon's Response to Medtronic's "Statement of Undisputed Facts" In Medtronic's Motion for Partial Summary Judgment for Invalidity of the '404 Patent Under 35 U.S.C. § 112

Pursuant to Local Rule 7.2(d)(3), Kyphon hereby responds to those facts relied on by Medtronic that Kyphon disputes. For the convenience of the Court, Kyphon will use the subheadings from Medtronic's brief.

A. The '724 Application

Medtronic Statement No. 1: On February 9, 1989, U.S.S.N. 308,724 "Surgical Protocol For Fixation Of Bone Using Inflatable Device" (the "'724 application") was filed by Arie Scholten and Mark Reiley.

Kyphon's Response: Undisputed (except that the '724 application was titled "Surgical Protocol For Fixation Of ***Osteoporotic*** Bone Using Inflatable Device" (emphasis added)).

Medtronic Statement No. 5: As its title made clear, the only method contemplated by the applicants in the '724 application for carrying out the "compacting" step was through the use of a balloon:

[Block quotation omitted for brevity.]

(Exh. 2.D, '888 Patent Prosecution History, Application, at 3 (February 9, 1989).)

Kyphon's Response: The use of a balloon was not the only method contemplated by the applicants in the '724 application. Claim 1, *as originally filed,* was never limited to using a balloon to form the claimed method. *See* discussion, *supra,* at IV.B; *see also* Kyphon Undisputed Fact 2. In addition, the passage is not accurately quoted, as it leaves out the term "osteoporotic" in two instances.

Medtronic Statement No. 6: The '724 application described the "compacting" step in great detail, exclusively in terms of the use of a balloon

[Block quotation omitted for brevity.]

(*Id.* at 11-13.)

Kyphon's Response: While it is true that the '724 application described the "compacting" step in great detail, and in terms of the use of a balloon, the claims of the '724 application were not so limited. *See* discussion, *supra,* at IV.B; *see also* Kyphon Undisputed Fact 2.

Medtronic Statement No. 7: The word "balloon" appears 42 times in the specification and "inflatable," "inflated" and "inflating" are collectively used 46 times.

Kyphon's Response: It is unclear to what "specification" Medtronic refers, and for that reason, this fact is disputed. The number of instances of the word "balloon" is correct for the specification of the '888 patent.

Medtronic Statement No. 8: The '724 application issued as U.S. Patent No. 4,969,888, "Surgical Protocol For Fixation Of Bone Using Inflatable Device," (the "'888 patent") on November 13, 1990. (Exh. 1.D, '888 Patent.)

Kyphon's Response: Undisputed (except that the '724 application issued as U.S. Patent No. 4,969,888, "Surgical Protocol For Fixation of ***Osteoporotic*** Bone Using Inflatable Device" (emphasis added)).

C. Kyphon's Related Patents

Medtronic Statement No. 13: In each patent referring to the '404 patent, Kyphon publicly confirmed that the '404 patent only disclosed a balloon for performing the compacting step:

[Block quotations and citations omitted for brevity.]

Kyphon's Response: Kyphon did not "publicly confirm that the '404 patent ***only*** disclosed a balloon for performing the compacting step" in its later-filed patents. *See* discussion, *supra,* at n.3. In addition, the passages were not accurately quoted for every patent cited. *See, e.g.,* U.S. Patent Nos. 6,979,341; 6,641,587; 6,607,544.

D. The *Disc-O-Tech* Case

Medtronic Statement No. 15: During the *Markman* proceedings, DOT argued that the "compacting" step in claim 1 should be interpreted so that its scope is limited to only involve balloons. (*See* Exh. 24, Special Master's Opinion and Order on Claim Construction, at 4.)

Kyphon's Response: Undisputed (except that Disc-O-tech argued in the preliminary injunction proceedings ***and*** the *Markman* proceedings that the "compacting" step in claim 1 should be interpreted so that its scope is limited to only involve ***inflatable*** (balloon) devices). [*See* Medtronic Ex. 24, Special Master's Opinion and Order on Claim Construction, at 4; *see also* Kyphon Ex. 62, *Kyphon Inc. v. Disc-O-Tech Medical Techs. Ltd.*, 2004 WL 2898064 at *4 (D. Del. 2004) (not reported in F. Supp. 2d.); Kyphon Undisputed Fact 17.]

Medtronic Statement No. 16: On May 16, 2005, a Special Master in the *DOT* case ruled that the claim 1 "compacting" step was not limited to only using a balloon. (*Id.* at 9.)

Kyphon's Response: Undisputed (except that the Special Mater ruled that the claim 1 "compacting" step was not limited to the use of ***inflatable*** (balloon) devices, and that ruling was adopted by the District Court. *See* Kyphon Undisputed Fact 18.

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of November 2006, I electronically filed

KYPHON'S OPPOSITION TO MEDTRONIC'S MOTION FOR PARTIAL SUMMARY JUDGMENT FOR INVALIDITY OF THE '404 PATENT UNDER 35 U.S.C. § 112 AND MEMORANDUM IN SUPPORT OF KYPHON'S MOTION FOR SUMMARY JUDGMENT OF NO INVALIDITY UNDER THE WRITTEN DESCRIPTION REQUIREMENT OF 35 U.S.C. § 112

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